

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT, INC., *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 4:20-cv-00283-O

**DEFENDANTS' RESPONSE TO PLAINTIFFS' SUPPLEMENTAL MOTION FOR
SUMMARY JUDGMENT AND SUPPLEMENTAL CROSS-MOTION FOR SUMMARY
JUDGMENT**

CHAD E. MEACHAM
United States Attorney

Brian W. Stoltz
Assistant United States Attorney
Texas Bar No. 24060668
1100 Commerce Street, Third Floor
Dallas, Texas 75242-1699
Telephone: 214-659-8626
Facsimile: 214-659-8807
brian.stoltz@usdoj.gov

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

CHRISTOPHER M. LYNCH
(D.C. Bar # 1049152)
Trial Attorney
U.S. Department of Justice
Civil Division
1100 L Street, NW
Washington, D.C. 20005
Telephone: (202) 353-4537
Fax: (202) 616-8460
Email: Christopher.M.Lynch@usdoj.gov

Attorneys for Defendants Xavier Becerra,
Janet L. Yellen, Martin J. Walsh, and the United States

TABLE OF CONTENTS

SUMMARY.....	1
ARGUMENT.....	1
I. PLAINTIFFS OTHER THAN BRAIDWOOD LACK STANDING TO CHALLENGE THE PREVENTIVE SERVICES PROVISION	1
A. The Religious Objector Plaintiffs Lack Standing Because They Do Not Participate in the Market for Health Insurance and the Challenged Coverages Thus Do Not Apply to Them	2
B. Plaintiffs Lack Standing Under the “Purchaser Standing” Doctrine	5
II. THE COURT SHOULD ENTER JUDGMENT FOR DEFENDANTS ON PLAINTIFFS’ CONTRACEPTIVE COVERAGE CLAIMS.....	7
III. THE COURT SHOULD PROVIDE BRAIDWOOD TARGETED RELIEF TAILORED TO ITS CLAIMS.....	8
A. Supreme Court Precedent Requires This Court To Sever the Provision that Makes § 300gg-13(a)(1) Unconstitutional, Authorizing the Secretary to Review PSTF’s Recommendations in the Future.....	8
B. Plaintiffs Are Not Entitled to a “Universal Remedy”	10
1. Plaintiffs Did Not Bring an APA Claim and Thus Are Not Entitled to an APA Remedy	11
2. By Their Own Admission, Plaintiffs Are Not “Eligible” for “Any Type of Universal Remedy” in This “Constitutional Challenge” to the “Legislature’s Action”	14
3. Plaintiffs Have Not Challenged the PSTF’s Authority to Issue Recommendations Under 42 U.S.C. § 299b(a)(1) and Are Not Entitled to Invalidation of Those Recommendations.....	15
4. Section 706(2) of the APA Does Not Authorize Vacatur As a Remedy.....	18
5. The “Universal Remedy” Requested by Plaintiffs Would Be Inappropriate Here Even if It Were Permissible	18

C. The Court Should Award Braidwood Targeted Relief Tailored to the Claims on Which It Prevailed	20
CONCLUSION	22

TABLE OF AUTHORITIES**Cases**

<i>Alley v. U.S. Dep't of Health & Hum. Servs.,</i> 590 F.3d 1195 (11th Cir. 2009)	19
<i>Arizona v. Biden,</i> 40 F.4th 375 (6th Cir. 2022)	18, 19
<i>Arizona v. Biden</i> 31 F.4th 469 (6th Cir. 2022)	20
<i>Citizens United v. FEC,</i> 558 U.S. 310 (2010)	13
<i>Coal. for Mercury-Free Drugs v. Sebelius,</i> 671 F.3d 1275 (D.C. Cir. 2012)	4, 5, 6, 7
<i>Croft v. Governor of Tex.,</i> 562 F.3d 735 (5th Cir. 2009)	3
<i>Cummings v. Premier Rehab Keller, P.L.L.C.,</i> 142 S. Ct. 1562 (2002)	12, 13
<i>Daniels Health Scis., L.L.C. v. Vascular Health Scis., L.L.C.,</i> 710 F.3d 579 (5th Cir. 2013)	21
<i>Data Mktg. P'ship LP v. U.S. Dep't of Labor,</i> 45 F.4th 846 (5th Cir. 2022)	12, 18
<i>Dep't of Homeland Sec. v. New York,</i> 140 S. Ct. 599 (2020)	20
<i>Driggers v. Business Men's Assurance Co. of Am.,</i> 219 F.2d 292 (5th Cir. 1955)	12, 13
<i>Ford v. NYLCare Health Plans of Gulf Coast, Inc.,</i> 301 F.3d 329 (5th Cir. 2002)	2
<i>Franciscan All., Inc. v. Becerra,</i> 47 F.4th 368 (5th Cir. 2022)	12
<i>Gill v. Whitford,</i> 138 S. Ct. 1916 (2018)	21
<i>Keener v. Convergys Corp.,</i> 342 F.3d 1264 (11th Cir. 2003)	19

<i>Louisiana v. Becerra</i> , 20 F.4th 260 (5th Cir. 2021).....	19, 20
<i>Lujan v. Defs. of Wildlife</i> , 504 U.S. 555 (1992)	2, 4
<i>Md. Shall Issue, Inc. v. Hogan</i> , 963 F.3d 356 (4th Cir. 2020)	5
<i>Salazar v. Buono</i> , 559 U.S. 700 (2010)	11
<i>Sapp v. Renfroe</i> , 511 F.2d 172 (5th Cir. 1975)	12
<i>Seila Law, LLC v. Consumer Fin. Prot. Bureau</i> , 140 S. Ct. 2183, 2209 (2020).....	10
<i>Trump v. Hawaii</i> , 138 S. Ct. 2392 (2018).....	19, 20
<i>United States v. Arthrex, Inc.</i> , 141 S. Ct. 1970 (2021).....	9, 10, 11, 21
<i>Valley Forge Christian Co., v. Am. United for Separation of Church and State, Inc.</i> , 454 U.S. 464 (1982)	5
<i>Weissman v. Nat'l R.R. Passenger Corp.</i> , 21 F.4th 854 (D.C. Cir. 2021)	2, 5, 6, 7

Statutes

5 U.S.C. § 703.....	18
5 U.S.C. § 706(2)	18
42 U.S.C. § 299b-4	<i>passim</i>
42 U.S.C. § 300gg-13	<i>passim</i>
42 U.S.C. § 1395m(n)(2)	17
42 U.S.C. § 1395x(ddd)	17

Rules

Fed. R. Civ. P. 26(e)(1)(A)	4
Fed. R. Civ. P. 37.....	4

Fed. R. Civ. P. 54(c) 13

Fed. R. Civ. P. 56(e) 2

Regulations

45 C.F.R. § 144.103 3

Coverage of Certain Preventive Services Under the Affordable Care Act,
78 Fed. Reg. 39,870 (July 2, 2013) 6

Other Authorities

John Harrison, *Section 706 of the Administrative Procedure Act Does Not Call for Universal Injunctions or Other Universal Remedies*,
37 Yale J, on Reg. Bull 37 (2020) 18

Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*,
131 Harv. L. Rev 417 (2017) 18

SUMMARY

In its September 7, 2022 Memorandum Opinion and Order, the Court concluded that one Plaintiff, Braidwood Management Inc. (“Braidwood”), had standing to assert its claims in this case. The Court also ruled that 42 U.S.C. § 300gg-13(a)(1) violates the Appointments Clause and that the requirement that Pre-Exposure Prophylaxis (“PrEP”) medications be covered by Braidwood’s self-insured health plan violates Braidwood’s rights under the Religious Freedom Restoration Act (“RFRA”). The Court ruled for Defendants on the merits of all Braidwood’s remaining claims. The Court has directed the parties to further brief: (1) the standing of other Plaintiffs; (2) Plaintiffs’ claims relating to the contraceptive coverage requirement pursuant to 42 U.S.C. § 300gg-13(a)(4); and (3) the scope of any remedy. *See* Scheduling Order re Suppl. Br. ECF No. 97.

Defendants respectfully submit that the remaining Plaintiffs lack standing. Most of those Plaintiffs do not participate in the health insurance market at all and so the challenged requirements do not affect them. In addition, the “purchaser standing” doctrine on which Plaintiffs rely does not afford them standing because the relevant product, as defined by its core features—health insurance—remains available to them despite the challenged law affecting ancillary aspects of that product. With respect to the contraceptive coverage claims, judgment must be entered for Defendants, as Plaintiffs concede; the Court has already rejected these claims on the merits, and, in any event, the remaining Plaintiffs lack standing to pursue the claims. Finally, the Court should issue a limited, targeted remedy to Braidwood that remedies the specific claims it prevailed upon, with the least disruption to Congress’ intended statutory scheme as applied to non-parties, because more “universal” relief is neither available nor appropriate here.

ARGUMENT

I. PLAINTIFFS OTHER THAN BRAIDWOOD LACK STANDING TO CHALLENGE THE PREVENTIVE SERVICES PROVISION

The seven plaintiffs other than Braidwood lack standing to bring their claims for two reasons. First, most of the remaining Plaintiffs do not participate in the health insurance market

for reasons other than the challenged coverage requirements, and thus, they are not injured by the requirements. Second, the sole legal ground that Plaintiffs claim affords them standing—the so-called “purchaser standing” doctrine—does not provide standing where, as here, plaintiffs retain the ability to purchase their desired product, as defined by its “core features.”¹ *Weissman v. Nat'l R.R. Passenger Corp.*, 21 F.4th 854, 859 (D.C. Cir. 2021). Plaintiffs do not dispute that health insurance that covers all services that they desire remains available to them. Therefore, they lack standing, even though health insurance excluding coverage of a handful of ancillary services they do not want is not available.

A. The Religious Objector Plaintiffs Lack Standing Because They Do Not Participate in the Market for Health Insurance and the Challenged Coverages Thus Do Not Apply to Them

None of the Plaintiffs asserting a religious objection to the coverage requirements at issue in this case has met its burden to establish standing. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (holding that “mere allegations” supporting standing are insufficient at summary judgment, and that plaintiffs must instead “‘set forth’ by affidavit or other evidence ‘specific facts’” that support their standing) (quoting Fed. R. Civ. P. 56(e)); *id.* (“The party invoking federal jurisdiction bears the burden of establishing the[] elements [of standing].”) (citation omitted); *see also Ford v. NYLCare Health Plans of Gulf Coast, Inc.*, 301 F.3d 329, 334 (5th Cir. 2002). To meet their burden, Plaintiffs must establish three elements: “(1) an ‘injury in fact’ that is (a) concrete and particularized and (b) actual or imminent; (2) a causal connection between the injury

¹ Plaintiffs John Kelley, Kelley Orthodontics, Joel Starnes, Zach Maxwell, and Ashley Maxwell (the “Religious Objector Plaintiffs”) assert both constitutional claims with respect to 42 U.S.C. § 300gg-13 (the “Preventive Services Provision”) and a RFRA claim with respect to the coverage requirement under 42 U.S.C. § 300gg-13(a)(1) for PrEP medications. *See* FAC ¶¶ 33-38, 53-57, 66-80, 108-111, ECF No. 14. Because they lack standing for the reasons set forth in Part I.A, the Court need not reach the arguments in Part I.B with respect to the Religious Objector Plaintiffs, although they also lack standing for the reasons set forth in Part I.B. Plaintiffs Joel Miller and Gregory Scheidman assert only constitutional claims with respect to 42 U.S.C. § 300gg-13. *See id.* ¶¶ 44-52, 66-80.

and the conduct complained of; and (3) the likelihood that a favorable decision will redress the injury.” *Croft v. Governor of Tex.*, 562 F.3d 735, 745 (5th Cir. 2009) (citation omitted).

None of the religious objector Plaintiffs can meet this burden, because none of them participates in the market for health insurance and they decline to do so for reasons other than the challenged requirements. Kelley and Starnes state that since 2016 they have participated in “Christian bill-sharing” programs that Plaintiffs do not dispute are not subject to the Preventive Services Provision²; Kelley Orthodontics has not provided health insurance to its employees at all since 2016. *See* APP 183-200, Nos. 1–56 (owner of Kelley Orthodontics admitting that “the premiums for health insurance that I provided for my employees increased, so much so that . . . I was forced to stop offering health insurance as a benefit because it was too expensive”); APP 206-220, Nos. 1–48 (Kelley admitting that “my health insurance premiums increased to a point where, in 2016 I stopped buying insurance”); APP 279-294, Nos. 1–48 (Starnes admitting that “my health insurance premiums increased to a point where, in 2016 I stopped buying insurance”). By their own admission, none of these plaintiffs has participated in the health insurance market since 2016, none has demonstrated that the challenged coverage requirements caused that decision, and none has demonstrated that a favorable ruling in this case would change that decision.

Plaintiffs’ only response is that they “want[] the option of purchasing conventional health insurance that excludes coverage of objectionable preventive care.” Suppl. Br. in Supp. of Pls.’ Mot. for Summ. J. (“Pls.’ Suppl. Br’). at 16, ECF No. 98 (citation omitted). But Plaintiffs do not establish that they would purchase such coverage if it were available, and wanting a product that

² The Preventive Services Provision applies to group health plans and health insurance issuers offering group or individual health insurance coverage. A health insurance issuer is defined in relevant part as an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act). *See* 42 U.S.C. § 300gg–91(b)(2) & 45 C.F.R. § 144.103. Christian bill-sharing arrangements, commonly known as health care sharing ministries, generally are not required to be licensed to engage in the business of insurance and generally are not subject to State law that regulates insurance.

one will not purchase to be available in the marketplace for others is not a cognizable injury. *See, e.g., Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1277 (D.C. Cir. 2012) (Kavanaugh, J.) (“[Plaintiffs] do not have standing to challenge FDA’s decision to allow *other people* to receive thimerosal-preserved vaccines.”).

Zach and Ashley Maxwell have also failed to show that they participate in the health insurance market or that the challenged coverage requirements have anything to do with that decision. In their June 2021 interrogatory responses, they indicated that they were “currently shopping for health insurance” but had not yet purchased it, having been without such insurance since January 2021. APP 397, ECF No. 65. In the intervening 17 months, Plaintiffs have not supplemented this response, despite an obligation to do so under Rule 26(e) and a request from Defendants that they do so. *See* Fed. R. Civ. P. 26(e)(1)(A) (“A party who . . . has responded to an interrogatory . . . must supplement or correct its disclosure or response . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing”); SUPP APP 001. Accordingly, the Court must assume that they still do not participate in the health insurance market and that they are not likely to imminently change that course. *See* Fed. R. Civ. P. 37(c)(1); *id.* 37(b)(2)(A)(i). In any event, they have not met their burden to establish that they participate in the health insurance market as required to establish standing here. *See, e.g., Lujan*, 504 U.S. at 563–64 (concluding plaintiffs lacked standing where they professed only “‘some day’ intentions” to visit the endangered species at issue).

In short, the religious objector Plaintiffs are attempting to litigate the regulation of a market they have chosen not to participate in, without showing that the Preventive Services Provision drove them out of or is keeping them from that market. They offer no basis on which they are aggrieved by the challenged requirements beyond an expression of disagreement with the law that imposes requirements on others. This does not confer standing. *See, e.g., Md. Shall Issue, Inc. v. Hogan*, 963 F.3d 356, 362 (4th Cir. 2020) (“MSI’s alleged injury is no more than a mere

disagreement with the policy decisions of the Maryland legislature, which is insufficient to meet the constitutional threshold for an injury in fact.”); *see also Coal. for Mercury-Free Drugs*, 671 F.3d at 1278-79 (“Standing protects democratic government by requiring citizens to express their generalized dissatisfaction with government policy through the Constitution’s representative institutions, not the courts.”); *Valley Forge Christian Co., v. Am. United for Separation of Church and State, Inc.*, 454 U.S. 464, 485-86 (1982) (The “observation of conduct with which one disagrees . . . is not an injury sufficient to confer standing under Art. III.”).

B. Plaintiffs Lack Standing Under the “Purchaser Standing” Doctrine

The exclusive legal ground on which Plaintiffs rely in contending that the non-Braidwood Plaintiffs have standing is the so-called “purchaser standing” doctrine. *See* Pls.’ Suppl. Br. at 11. Plaintiffs claim that this doctrine “allows litigants to sue whenever a statute or agency action deprives them of the opportunity to purchase a desired product.” *Id.* But the Fifth Circuit has never adopted the purchaser standing doctrine. And the D.C. Circuit precedent on which Plaintiffs exclusively rely has “assumed” that the doctrine permits standing “only in the context of a challenge . . . under the [Administrative Procedure Act (“APA”)],” which is not at issue here. *Weissman*, 21 F.4th at 859. In any event, “[e]ven assuming” the purchaser standing doctrine applied in the Fifth Circuit and “could apply beyond [the APA] context,” it would still not apply here.

The D.C. Circuit’s recent *Weissman* decision rejects the premise behind Plaintiffs’ maximalist construction of the purchaser standing doctrine. In *Weissman*, plaintiffs sought to challenge Amtrak’s decision to modify the terms and conditions governing its rail service to include a mandatory arbitration provision. *Id.* at 856. In an effort to establish standing, the *Weissman* plaintiffs—like Plaintiffs here—“rel[ied] on [the D.C. Circuit’s] precedent that consumers have standing to challenge government action that ‘prevented the consumers from purchasing a desired product.’” *Id.* at 857 (quoting *Coal. for Mercury-Free Drugs*, 671 F.3d at 1281). The court rejected plaintiffs’ contention, analyzing the very cases on which Plaintiffs rely here to explain the limits of the purchaser standing doctrine:

In each case, the court analyzed the injury-in-fact requirement by considering whether government action had meaningfully abridged a concrete interest of the plaintiff in accessing the desired product. That inquiry has focused on two considerations: whether the challenged action made a consumer's desired product, *as defined by its core features*, "not readily available," and whether it rendered the product "unreasonably priced."

Weissman, 21 F.4th at 858 (quoting *Coal. for Mercury-Free Drugs*, 671 F.3d at 1282) (emphasis added). In *Weissman*, as here, plaintiffs did not and could not show that the challenged decision made the product at issue more expensive or unreasonably priced. *See id.* at 859; Defs.' Br. in Supp. of Resp. to Pls.' Mot. for Summ. J. & Cross-Mot for Summ. J. ("Defs.' Br.") at 11-20, ECF No. 64; *see also* Resp. to Defs.' Mot for Summ. J. & Reply Br. in Supp. of Pls.' Mot. for Summ. J. at 3-4, ECF No. 74; *id.* at 6 ("The allegations of the plaintiffs' complaint [that the coverage requirements increased the cost of health insurance] are not relevant at this stage of the litigation."); *see also* Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,872 (July 2, 2013) ("Use of preventive services results in a healthier population and reduces health care costs by helping individuals avoid preventable conditions and receive treatment earlier."). Instead—again, like Plaintiffs here, who argue that health insurance without certain preventive services coverage is no longer on the market, Br. in Supp. of Pls.' Mot. for Summ. J. at 9-10, ECF No. 45—the *Weissman* plaintiffs "maintain[ed] that, . . . they are prevented from purchasing their desired product because an Amtrak rail ticket without an arbitration clause is no longer on the market as a result of Amtrak's new term of service." *Weissman*, 21 F.4th at 859.

But, the D.C. Circuit explained, this was not sufficient to establish standing. Rather, "the product at issue" must be "differentiated from available alternatives by its core features," not ancillary ones. *Id.* Thus, the *Weissman* plaintiffs "adequately alleged a 'primary,' concrete consumer interest in traveling on Amtrak, but not in purchasing an Amtrak ticket without an arbitration provision." *Id.* at 860. So too here. Plaintiffs may have a primary interest in obtaining health insurance, but not in obtaining health insurance that excludes coverage for ancillary preventive services they have no intention of using.

The *Weissman* court further explained that “[c]onsumers proceeding on a desired-products theory must still allege a concrete invasion of a cognizable interest,” and that, again like Plaintiffs here, the *Weissman* plaintiffs “failed to do so” because they did not demonstrate how any harm from the mere existence of this ancillary term of service (i.e., an arbitration provision) is “‘actual or imminent,’ not ‘conjectural’ or ‘hypothetical.’” *Id.* at 859 (citation omitted).

In short, Plaintiffs’ “approach would contrive standing simply by redefining any sweeping ‘gripe’ as the inability to obtain a product that negates that ‘gripe,’ which would contravene a central purpose of Article III standing doctrine to channel ‘generalized dissatisfaction with government policy’ into the political process, not the courts.” *Id.* at 860 (quoting *Coal. for Mercury-Free Drugs*, 671 F.3d at 1278). Plaintiffs’ requested “unbounded expansion of the desired-products theory, then, would circumvent much of modern standing doctrine, allowing abstract and speculative interests to find a footing for standing merely by reframing their injury as a lost opportunity to purchase a product.” *Id.* at 861.

Plaintiffs do not even acknowledge *Weissman* or respond in their brief to the limitations on the “purchaser standing” doctrine it establishes, despite Defendants raising the case in prior briefing and at the hearing on the parties’ cross motions for summary judgment. *See* Defs.’ Reply in Supp. of Cross-Mot. for Summ. J. (“Defs.’ Reply”) at 3-5, ECF No. 83; July 26, 2022 Hrg. Tr. 31:4-32:4. Plaintiffs may desire health insurance that excludes coverage of a small number of ancillary services, but that is not sufficient to establish standing when there is no dispute that health insurance covering the services Plaintiffs *do* want is available to them. Having failed to demonstrate a concrete injury here, Plaintiffs do not have standing to bring their claims.³

II. THE COURT SHOULD ENTER JUDGMENT FOR DEFENDANTS ON PLAINTIFFS’ CONTRACEPTIVE COVERAGE CLAIMS

Defendants agree with Plaintiffs that, pursuant to the Court’s Memorandum Opinion and

³ To the extent not restated herein, Defendants reassert and incorporate by reference their arguments related to standing in their prior summary judgment briefing. *See* Defs.’ Br. at 9-26; Defs.’ Reply at 2-10.

Order of September 7, 2022 (ECF No. 92), the Court should enter judgment for Defendants on Plaintiffs' contraceptive coverage claims. In that order, the Court ruled that Plaintiff Braidwood had standing to bring its Appointments Clause and nondelegation claims challenging 42 U.S.C. § 300gg-13(a)(4) but rejected both claims on the merits. To the extent the Court finds that any other plaintiff has standing, Defendants respectfully submit that the Court's prior opinion compels a ruling for Defendants on the merits of these claims. However, for the reasons set forth in Part I, above, Defendants respectfully submit that the remaining Plaintiffs lack standing to assert their contraceptive coverage claims (in addition to their other claims), and that those claims should be dismissed for that reason. *See supra* Part I.

III. THE COURT SHOULD PROVIDE BRAIDWOOD TARGETED RELIEF TAILORED TO ITS CLAIMS

A. Supreme Court Precedent Requires This Court To Sever the Provision that Makes § 300gg-13(a)(1) Unconstitutional, Authorizing the Secretary to Review PSTF's Recommendations in the Future

As Defendants explained in their prior briefing, *see* Defs.' Br. at 46-48 & Defs.' Reply at 26-28, the proper cure for any Appointments Clause violation resulting from 42 U.S.C. § 300gg-13(a)(1) is not to invalidate any coverage requirements under that section.⁴ Rather, the Court should disregard the portion of the Preventive Services Task Force's ("PSTF") enabling statute that limits the Secretary's authority over the PSTF's recommendations with respect to the Preventive Services Provision. *See* 42 U.S.C. § 299b-4(a)(6) ("All members of the [PSTF], and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure."). Disregarding this provision cures in full any Appointments Clause violation from the Preventive Services Provision by allowing the Secretary to review the PSTF's recommendations, just as the Secretary can review guidelines of ACIP and HRSA under the other portions of the Preventive Services Provision, which the Court concluded do not violate

⁴ Although Defendants recognize the Court's ruling on the parties' motions for summary judgment and submit that the remedies proposed herein are appropriate in light of that ruling, Defendants respectfully maintain that there is no Appointments Clause or RFRA violation and that no remedy is necessary.

the Appointments Clause. *See* Sept. 7, 2022 Mem. Op & Order at 42, ECF No. 92.

The Supreme Court made clear that this is the appropriate remedy in its recent decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021). There, the Court held that because Administrative Patent Judges on the Patent Trial and Appeal Board (“PTAB”) had “unreviewable authority . . . during *inter partes* review,” their appointment to inferior office was unconstitutional. *Id.* at 1985. In resolving the case, however, the Court declined “to hold the entire regime of *inter partes* review unconstitutional.” *Id.* at 1986. Instead, the Court explained,

“[W]hen confronting a constitutional flaw in a statute, we try to limit the solution to the problem” by disregarding the “problematic portions while leaving the remainder intact.” This approach derives from the Judiciary’s “negative power to disregard an unconstitutional enactment” in resolving a legal dispute. In a case that presents a conflict between the Constitution and a statute, we give “full effect” to the Constitution and to whatever portions of the statute are “not repugnant” to the Constitution, effectively severing the unconstitutional portion of the statute.

Id. (citations omitted).

Accordingly, the Court held that in keeping with the PTO Director’s statutory authority, which vests the Director with “the powers and duties” of the PTO, it would remedy the Appointments Clause defect by invalidating the statute that prohibited the Director from reviewing the PTAB’s decisions. *Id.* (citation omitted). That remedy would permit the *inter partes* review scheme to continue as before but would place the ultimate review in a constitutionally appointed principal officer of the United States. *Id.*; *see id.* at 1987-88. The Court then remanded the case to the Acting Director of the PTO for review of the PTAB’s decision. In other words, the Court held that the remedy for a statutory scheme giving unreviewable authority of sufficient importance to an officer that was not appointed by the President and confirmed by the Senate is to require that a principal officer have the opportunity to review the actions previously performed by personnel who were not appointed pursuant to constitutional requirements, leaving the rest of the statute intact.

Arthrex mandates the same approach here. The Court ruled the Secretary’s inability to review the recommendations of the PSTF violated the Appointments Clause, which the Court determined left the PSTF with authority to make a final decision on what preventive services must

be covered pursuant to 42 U.S.C. § 300gg-13(a)(1). Just as in *Arthrex*, disregarding the statutory restriction on a principal officer’s review (i.e., 42 U.S.C. § 299b-4(a)(6)) cures the Appointments Clause violation, while doing the least violence possible to the constitutional portions of Congress’ carefully constructed statutory scheme.

In their merits briefing, Plaintiffs contended that the Preventive Services Provision is analogous to the *inter partes* regime at issue in *Arthrex*, vesting unreviewable discretion in improperly appointed officers. *See, e.g.*, Br. in Supp. of Pls. Mot. for Summ. J at 12; *id.* at 14 (“It is hard to conceive of ‘authority’ more ‘significant’ than the power to unilaterally dictate the scope of preventive care that private insurers must cover, without any cost-sharing arrangements such as deductible or copays.”). It follows that *Arthrex*’s remedy applies—the Secretary as a Senate-confirmed officer must have authority to review and approve PSTF recommendations for the Preventive Services Provision coverage requirements to continue in effect. Thus, the Court should hold 42 U.S.C. § 299b-4(a)(6) unenforceable to the extent it precludes the Secretary’s review and approval of PSTF’s recommendations for purposes of the Preventive Services Provision’s coverage requirements, but no further tinkering with the statute or invalidation of agency action need or should be done. *See also Seila Law, LLC v. Consumer Fin. Prot. Bureau* 140 S. Ct. 2183, 2209 (2020) (“[W]hen confronting a constitutional flaw in a statute, we try to limit the solution to the problem, severing any problematic portions while leaving the remainder intact.”) (citation omitted); *id.* at 2210-11 (“We think it clear that Congress would prefer that we use a scalpel rather than a bulldozer in curing the constitutional defect we identify today.”).

B. Plaintiffs Are Not Entitled to a “Universal Remedy”

Instead of the straightforward remedy mandated by the Supreme Court in *Arthrex*, Plaintiffs propose a sweeping invalidation of numerous regulations and recommendations that would create extraordinary upheaval in the United States’ public health system. Beyond the reason explained above—that *Arthrex* requires a particular, and narrow, remedy other than the broad one Plaintiffs request, *see* Part III.A, *supra*—Plaintiffs’ proposal fails for numerous reasons. First, Plaintiffs did not bring an APA claim and thus are not entitled to an APA remedy. Second,

Plaintiffs brought and prevailed on a “constitutional challenge to section 300gg-13(a)([1]) alleg[ing] that *Congress* violated the Constitution by enacting this statute.” Br. in Opp’n to Defs.’ Mot. to Dismiss at 13-14, ECF No. 24 (citation omitted). By Plaintiffs’ own admission, a constitutional challenge to Legislative action is “not . . . eligible for . . . any type of universal remedy.” Pls. Suppl. Br. at 10. Third, the Court cannot invalidate PSTF recommendations issued pursuant to a statute that Plaintiffs have not challenged and the validity of which the Court has not considered here. Fourth, even if Plaintiffs had brought and succeeded on an APA claim addressing the validity of the PSTF’s recommendations themselves (which they have not), the APA does not authorize “universal relief” of the type sought by Plaintiffs. Finally, even if authorized (which it is not), the “universal remedy” sought by Plaintiffs would be inappropriate here.

1. Plaintiffs Did Not Bring an APA Claim and Thus Are Not Entitled to an APA Remedy

In their supplemental brief, Plaintiffs contend that they are entitled to a “universal remedy” vacating “all [PSTF] recommendations with ‘A’ or ‘B’ ratings that were issued on or after March 23, 2010” and “all other agency action taken to implement those . . . recommendations.” Pls.’ Suppl. Br. at 9. Plaintiffs assert that the APA provides “a veto-like power that enables the judiciary to formally revoke an agency’s rules, orders, findings, or conclusions.” *Id.* at 7. Even if Plaintiffs’ view of available APA remedies were correct (and it is not, *see* Part III.B.4, *infra*), any such remedies are not permitted here for the simple reason that Plaintiffs neither brought, nor prevailed on, an APA claim. The specific remedies set forth in the APA thus do not apply in this case. *See, e.g., Salazar v. Buono*, 559 U.S. 700, 718 (2010) (“A court must find prospective relief that fits the remedy to the wrong or injury that has been established.”).

Plaintiffs cite no case awarding an APA remedy where the plaintiff did not bring an APA claim. In the two cases they do cite, the plaintiff brought claims under the APA challenging agency action. *See Data Mktg. P’ship LP v. U.S. Dep’t of Labor*, 45 F.4th 846, 851 (5th Cir. 2022) (explaining “three questions presented” are whether challenged DOL action “is reviewable ‘final agency action’ under the [APA] . . . whether [that] action is “arbitrary, capricious, or otherwise

contrary to law,” and whether vacatur is “the appropriate relief”); *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 374 (5th Cir. 2022) (“The 2020 Rule gave Franciscan Alliance the remedy an APA violation called for—vacatur of the 2016 Rule’s prohibition of discrimination on the basis of ‘termination of pregnancy’ and ‘gender identity.’ Franciscan Alliance’s APA claim sought nothing more.”). In contrast, not only did Plaintiffs here not bring an APA claim, they also expressly disclaimed that they were challenging agency action. *See infra* Part III.B.2; Br. in Opp’n to Defs.’ MTD at 13-14 (“The constitutional challenge to section 300gg-13(a)(4) alleges that *Congress* violated the Constitution by enacting this statute. It challenges the *legislature’s* action in enacting a law There is no concern with how [HHS] decides to use its powers under the statute; that is irrelevant to the Appointments Clause . . . challenge[] alleged in the first amended complaint.”) (citation omitted).

Plaintiffs appear to argue in a footnote that they need not have mentioned the APA remedy explicitly in their Complaint’s prayer for relief as long as they prevail on a claim that entitles them to that relief. *See* Pls.’ Supp Br. at 9 n.6 (“Courts must award the relief to which a party is entitled regardless of whether it asked for that relief in its pleadings.”). But that principle does not help Plaintiffs when their operative complaint does not invoke the APA or even mention the APA at all. To be sure, there may be cases where plaintiffs prevail on a claim that they have asserted in their complaint and obtain relief authorized for that claim that is not explicitly requested in their prayer for relief, particularly when their prayer for relief includes a catchall provision. *See e.g.*, *Sapp v. Renfroe*, 511 F.2d 172, 176 n.3 (5th Cir. 1975); *Driggers v. Business Men’s Assurance Co. of Am.*, 219 F.2d 292, 299 (5th Cir. 1955). But that principle does not permit Plaintiffs to obtain relief for claims they never pleaded nor proved. Thus, a plaintiff cannot assert a breach of contract claim and then, after prevailing, obtain tort remedies like punitive damages without ever pleading or proving a tort claim. *See, e.g.*, *Cummings v. Premier Rehab Keller, P.L.L.C.*, 142 S. Ct. 1562, 1571 (2002) (“It is hornbook law that . . . punitive damages . . . are generally not available for breach of contract[.]”). Plaintiffs’ contrary rule would violate basic principles of both notice pleading and due process.

Rule 54(c) does not help Plaintiffs, either. To be sure, as Plaintiffs note, Rule 54(c) provides that a “final judgment should grant the relief to which each party is entitled, even if the party has not demanded that relief in its pleadings.” Fed. R. Civ. P. 54(c). But Rule 54 in no way suggests that a party “is entitled” to relief available for claims the party never brought, never supported with evidence, and never prevailed upon. *See, e.g., Driggers*, 219 F.2d at 299 (“[T]he final judgment should grant the relief to which plaintiff may *prove* himself entitled, even if he has not demanded such relief in his pleadings.”) (emphasis added). Nor does Plaintiffs’ citation to *Citizens United v. FEC*, 558 U.S. 310 (2010) have any bearing on the question here. The issue discussed there was whether, given that “[a]ll concede that [a First Amendment] claim [wa]s properly before” the Supreme Court and had been asserted “throughout the litigation,” 558 U.S. at 330, the Court could address whether the statute was facially invalid under the First Amendment and, if so, provide an appropriate remedy, rather than simply addressing whether the statute was invalid as applied. *See id.* at 331 (“The parties cannot enter a stipulation that prevents the Court from considering certain remedies if those remedies are necessary to resolve *a claim that has been preserved*.”) (emphasis added). Here, no APA claim is properly before the Court and no APA claim has been preserved, nor has the Court awarded judgment on any such claim, so no APA-specific remedies are available to Plaintiffs.

This rule has all the more force in the present case, because Plaintiffs initially brought an APA claim but abandoned it in response to Defendants’ initial motion to dismiss. *Compare* Compl. ¶¶ 98-102, ECF No. 1 *with* FAC ¶¶ 66-111 (asserting claims under the Appointments Clause, nondelegation doctrine, Vesting Clause, 42 U.S.C. § 300gg-13 itself, and RFRA, but not the APA); *see* Defs.’ Mot. to Dismiss at 21-27, ECF No. 12 (“The Challenged Coverage Requirements Do Not Violate the APA’s Notice and Comment Requirements”). By their actions, Plaintiffs withdrew the APA as an issue for the case rather than have their APA claim tested for legal sufficiency. They cannot now seek remedies specific to the withdrawn claim at the close of district court litigation. Whatever remedies the APA may provide for plaintiffs who plead, prove, and prevail on APA claims, it does not afford any remedy to Plaintiffs here, who did none of those things.

2. By Their Own Admission, Plaintiffs Are Not “Eligible” for “Any Type of Universal Remedy” in This “Constitutional Challenge” to the “Legislature’s Action”

Plaintiffs, by their own admission, are not entitled to the putative APA remedy they seek in this case. They concede that “Braidwood would not be eligible for a nationwide injunction (*or any type of universal remedy*) if it were merely challenging the constitutionality of a statute or ordinance” and would only be entitled to the “universal remedy” Plaintiffs seek if it “challenge[d] unlawful agency action.” Pls.’ Suppl. Br. at 10 (emphasis added). But Plaintiffs have forcefully argued that their constitutional claims challenge *only* the constitutionality of a statute, and *not* allegedly unlawful agency actions. As they explained in their opposition to Defendant’s motion to dismiss:

The constitutional challenge to section 300gg-13(a)(4) alleges that *Congress* violated the Constitution by enacting this statute. It challenges the *legislature’s* action in enacting a law that confers authority on individuals who are not appointed in conformity with Article II The “nucleus” of relevant facts concerns the text of this statute and the meaning of the Constitution—nothing more. The alleged constitutional violation occurred at the moment of the statute’s enactment, and the “nucleus” of relevant facts is centered around that event and nothing else. There is no concern with how HRSA decides to use its powers under the statute; that is irrelevant to the Appointments Clause and nondelegation challenges alleged in the first amended complaint. *See* First Amended Complaint (ECF No. 14) at ¶¶ 66–89.

Br. in Opp’n to Defs.’ MTD at 13-14 (emphasis in original; footnotes omitted). Plaintiffs contrasted their Appointments Clause claim in this case with prior, related litigation. That prior litigation, in their words:

Challeng[ed] *only* the behavior of *executive branch officials* The relevant facts concerned . . . the conduct of the executive branch, which ha[s] nothing to do with *any* of facts surrounding the plaintiffs’ constitutional challenges to section 300gg- 13(a)(4). There is no overlap at all with these factual nuclei

Id. at 14 (emphasis in original); *see id.* at 10 (“[T]he plaintiffs in this case are challenging the constitutionality of the underlying statutes that authorize HRSA (and other entities) to impose preventive-care coverage mandates on private insurers. This is not the ‘same claim’ or the ‘same

cause of action’ that was asserted in *DeOtte*, which concerned only the failure of the Contraceptive Mandate to provide sufficient exemptions for religious objectors.”); *id.* at 11 (“*Hellerstedt* also makes clear that a challenge to the constitutionality of 42 U.S.C. § 300gg-13(a)(4) is not ‘the very same claim’ as the RFRA challenges in *DeOtte* because section 300gg-13(a)(4) is a ‘separate, distinct provision’ from the agency rules that were challenged in the *DeOtte* litigation.”) (citation omitted); *id.* at 12 (“section 300gg-13(a)(4) and the agency rules challenged in *DeOtte* are far more “separate” and “distinct” from each other than the abortion-related statutory provisions in *Hellerstedt*. Section 300gg-13(a)(4) is a statutory provision enacted in 2010 as part of the Affordable Care Act. The Contraceptive Mandate is a series of agency rules that post-date the enactment of section 300gg-13(a)(4)”).

Because, as Plaintiffs concede, the Appointments Clause claim on which Braidwood prevailed challenges the legislature’s action, not any action of the PSTF or other agency officials, Br. in Opp’n to Defs.’ MTD at 13, Plaintiffs are, by their own admission, “not . . . eligible for a nationwide injunction (or any type of universal remedy).”⁵ Pls.’ Suppl. Br. at 10.

3. Plaintiffs Have Not Challenged the PSTF’s Authority to Issue Recommendations Under 42 U.S.C. § 299b(a)(1) and Are Not Entitled to Invalidation of Those Recommendations

Even if Plaintiffs had not conceded both (a) that their Appointments Clause claim challenges the constitutionality of a statute and not the actions of administrative agencies and (b) that such a scenario precludes them from obtaining the “universal relief” they now seek, Plaintiffs would still not be entitled to the particular universal relief that they seek here. That is because while Plaintiffs ask the Court to invalidate certain “A” and “B” recommendations of the PSTF,

⁵ To be sure, in contrast to its constitutional claim, Braidwood’s RFRA claim does relate to the actions of the PSTF. But that claim cannot be a basis for a “universal remedy” even with respect to PrEP (the only coverage requirement challenged under RFRA). The RFRA claim does not challenge the validity of the PrEP requirement itself, but only the application of that requirement to Braidwood in light of Braidwood’s specific religious objections. Plaintiffs do not appear to dispute this: They make no argument that Braidwood’s PrEP claim entitles it to “universal” relief with respect to PrEP or any other requirement. Accordingly, there appears to be no dispute that any relief awarded for Braidwood’s RFRA claim must apply only to Braidwood.

Plaintiffs have never argued, let alone demonstrated, that those recommendations were improperly issued.

As noted above, Plaintiffs have made clear that they claim “*Congress* violated the Constitution by enacting [the Preventive Services Provision]” and “challenge the *legislature’s* action in enacting a law that confers authority on individuals who are not appointed in conformity with Article II.” Br. in Opp’n to Defs.’ MTD at 13. But the Preventive Services Provision is not the statute that authorizes the PSTF *to make recommendations*, and a successful challenge to the Preventive Services Provision does not undermine the PSTF’s authority to make recommendations. All the Preventive Services Provision does is establish that “[a] group health plan and a health insurance issuer offering group or individual health insurance coverage shall . . . provide coverage for and shall not impose any cost sharing requirements for” certain recommendations of the PSTF. 42 U.S.C. § 300gg-13(a)(1). A successful claim that this statute is unconstitutional, then, may warrant excusing Plaintiffs from complying with the *coverage requirements* the statute imposes on any Plaintiffs with standing to challenge those requirements (in this case, only Braidwood, *see Part I, supra*), but it does not provide any basis to invalidate the PSTF’s recommendations themselves.

By contrast, the PSTF is authorized to issue recommendations pursuant to a different statute, 42 U.S.C. § 299b-4(a)(1). That statute provides that the PSTF “shall . . . develop[] recommendations for the health care community, and update[e] previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services.” *Id.* In making these recommendations, the PSTF must “consider clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.” *Id.* Plaintiffs do not claim that the PSTF acted contrary to this statute in issuing its recommendations or that the statute is unlawful.

Further, the PSTF’s recommendations are made and used for other purposes besides the Preventive Services Provision’s coverage requirements. For example, the Medicare statute makes

use of the PSTF’s recommendations in a variety of ways, including establishing a menu of services for which the Secretary can in his or her discretion authorize coverage. *See* 42 U.S.C. § 1395m(n)(2) (“if the Secretary determines appropriate, the Secretary may . . . provide that no payment shall be made under this subchapter for a preventive service described in [a section of the Medicare statute] that has not received a grade of A, B, C, or I by such Task Force.”); 42 U.S.C. § 1395x(ddd) (providing the Secretary discretion to expand the scope of “additional preventive services” under Medicare Part B to include services that are recommended by the USPSTF with a grade of A or B). In addition, the PSTF’s recommendations are used by non-government medical professionals for clinical purposes in deciding how best to provide care to their patients. *See* 42 U.S.C. § 299b-4(a)(1) (The PSTF is charged with the “purpose of developing recommendations for the health care community, . . . to be published in the Guide to Clinical Preventive Services . . . , for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives.”). Vacating the PSTF’s “A” and “B” ratings issued after March 23, 2010, as Plaintiffs request, would disrupt these other purposes and programs that have not been the subject of this litigation even though the Court has not considered these programs or provisions or determined any of them to run afoul of the Appointments Clause.

In sum, Plaintiffs have never claimed that the PSTF is not authorized to issue recommendations pursuant to Section 299b-4(a)(1), nor have they claimed that any particular PSTF recommendation was improperly issued. The Court, moreover, has never addressed the merits of any such claim. Accordingly, there is no basis to invalidate *any* recommendation issued by the PSTF or any “agency action taken to implement those Task Force recommendations.” Pls.’ Supp. Br. at 9.

4. Section 706(2) of the APA Does Not Authorize Vacatur As a Remedy

As demonstrated above, Plaintiffs are not entitled to a “universal remedy” such as vacatur under Section 706(2) of the APA in this case, regardless of whether Section 706(2) authorizes such remedies in some cases. Although Defendants recognize that the Fifth Circuit has previously accepted the argument that 5 U.S.C. § 706(2) authorizes vacatur of an agency action, *see Data Mktg. P’ship, LP*, 45 F.4th at 859-60, Defendants respectfully contend that it does not. Section 706(2) is merely a rule of decision directing the reviewing court to disregard unlawful agency action in resolving the case before it; the provision does not dictate any particular remedy. *See* Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 Harv. L. Rev 417, 451-52 (2017); *see id.* at 438 n. 121. Instead, APA remedies are governed by a different provision, Section 703, which provides that some APA cases are governed by a “special statutory . . . proceeding,” where vacatur may be available, or, in the absence of such statute, governed by a traditional “form of legal action,” such as “actions for declaratory judgments or writs of prohibitory or mandatory injunction.” 5 U.S.C. § 703; *see* John Harrison, *Section 706 of the Administrative Procedure Act Does Not Call for Universal Injunctions or Other Universal Remedies*, 37 Yale J. on Reg. Bull 37, 37, 39-40 (2020); *see also* *Arizona v. Biden*, 40 F.4th 375, 396 (6th Cir. 2022) (Sutton, C.J., concurring) (Section 706(2)’s language that “a reviewing court may ‘hold unlawful and set aside’ agency actions that violate the law . . . raises a question; it does not answer it. The question is whether Congress meant to upset the bedrock practice of case-by-case judgments with respect to the parties in each case or create a new and far-reaching power through this unremarkable language.”).

5. The “Universal Remedy” Requested by Plaintiffs Would Be Inappropriate Here Even if It Were Permissible

While Plaintiffs argue that they are entitled to a nationwide injunction, they predicate that contention exclusively on their purported entitlement to APA remedies. Pls.’ Suppl. Br. at 9-10. Accordingly, there is no dispute that if Plaintiffs are not entitled to any APA remedy, they are not entitled to a nationwide injunction. Because Defendants have demonstrated that Plaintiffs are not

entitled to APA remedies, Plaintiffs have no basis for obtaining a nationwide injunction. *See supra* Parts III.B.1-3.

Nor is a nationwide injunction appropriate here. The Fifth Circuit has made clear that universal remedies like nationwide injunctions are not “required or even the norm.” *Louisiana v. Becerra*, 20 F.4th 260, 263 (5th Cir. 2021). Instead, they “must be justified based on the circumstances.” *Id.* (quotation marks omitted). Thus, “[i]njunctive relief should be limited in scope to the extent necessary to protect the interests of the parties,” and “[i]t is well-settled that a district court abuses its discretion when it drafts an injunction that is unnecessarily broad in scope.” *Alley v. U.S. Dep’t of Health & Hum. Servs.*, 590 F.3d 1195, 1205 (11th Cir. 2009) (quoting *Keener v. Convergys Corp.*, 342 F.3d 1264, 1269 (11th Cir. 2003)). Indeed, “a district court should think twice—and perhaps twice again—before granting universal anti-enforcement injunctions against the federal government.” *Arizona*, 40 F.4th at 396 (Sutton, C.J., concurring). This is because “universal remedies . . . seem to take the judicial power beyond its traditionally understood uses, permitting district courts to order the government to . . . refrain from acting toward nonparties in the case” even though “[t]he law already has a mechanism for applying a judgment to third parties,” the class action. *Id.* Such remedies “create practical problems too,” by “incentive[izing] forum shopping,” and “short-circuit[ing] the decisionmaking benefits of having different courts weigh in on vexing questions of law,” “lead[ing] to rushes to judgment” and “load[ing] more and more carriage on the emergency dockets of the federal courts.” *Id.*; *see also Trump v. Hawaii*, 138 S. Ct. 2392, 2425-26, 2429 (2018) (Thomas, J., concurring) (noting the Justice’s “skept[icism] that district courts have the authority to enter universal injunctions” because they “do not seem to comply with th[e] principles” of equity and because “[n]o persuasive defense has yet been offered for the practice” of issuing them); *see generally id.* at 2424-29; *Dep’t of Homeland Sec. v. New York*, 140 S. Ct. 599, 599-601 (2020) (Gorsuch, J., concurring) (same). Plaintiffs have not made any showing that the extraordinary circumstances that might authorize such an extreme remedy exist in this case.

However, there are numerous reasons why a nationwide injunction or any other “universal

remedy” is not appropriate here. First, Plaintiffs chose not to pursue a class action. Indeed, their initial complaint purported to do just that, but Plaintiffs abandoned that path. *Compare* Compl. ¶¶ 126-147 *with* FAC. Plaintiffs should not be permitted to do an end-run around Rule 23’s requirements simply because the United States is a defendant. Second, of the many Plaintiffs here, only one has been able to establish cognizable harm from the challenged coverage requirements. By contrast, the coverage requirements provide a benefit to millions of consumers of insurance. They also provide predictability to those who participate in health insurance and self-insured group plans, so that insurers and group plans know what they must cover and consumers know what preventive services they can obtain cost free. In these circumstances, it is particularly appropriate to permit the issue to percolate through the courts to a definitive ruling from a court of last resort, rather than thrusting the entire health insurance system into uncertainty because a single plaintiff (or even a handful of plaintiffs) prevailed on an individual, non-class claim. *Cf. Louisiana*, 20 F.4th at 264 (“This vaccine rule is an issue of great significance currently being litigated throughout the country. Its ultimate resolution will benefit from ‘the airing of competing views’ in our sister circuits.” (citation omitted)). In the meantime, targeted relief can ensure that the one Plaintiff who has demonstrated standing and entitlement to relief will be excused from compliance with the challenged requirements.⁶

C. The Court Should Award Braidwood Targeted Relief Tailored to the Claims on Which It Prevailed

Because Plaintiffs are not entitled to either vacatur or any other “universal” remedy, the remedy must be limited to a declaration and injunction in favor of Braidwood, the only Plaintiff to

⁶ Defendants agree with Plaintiffs that any declaratory relief must likewise be limited to a declaration of the specific rights and legal relations of the Plaintiffs who have individually demonstrated they have standing to sue and Defendants. *See* Pls.’ Supp. Br. at 4-7. This limitation provides further reason that the Court should limit any injunctive relief to the same parties: It makes no sense to declare the rights of the parties only to issue an injunction that prevents enforcement against *anyone* in the United States. *Cf. Arizona v. Biden*, 31 F.4th 469, 483 (6th Cir. 2022) (Sutton, C.J., concurring) (“A valid Article III remedy operates with respect to specific parties, not with respect to law in the abstract” which is “why courts generally grant relief in a party-specific and injury-focused manner.”) (quotations and citations omitted).

have established standing. Further, the substance of that declaration and injunction must be specific to the claims that Braidwood prevailed upon. *See, e.g., Gill v. Whitford*, 138 S. Ct. 1916, 1933-34 (2018) (explaining that “[a] plaintiff’s remedy must be tailored to redress the plaintiff’s particular injury”); *see also Daniels Health Scis., L.L.C. v. Vascular Health Scis., L.L.C.*, 710 F.3d 579, 586 (5th Cir. 2013) (Courts “must narrowly tailor an injunction to remedy the specific action which gives rise to the order.”) (citation omitted). There are two such claims. First, the Court ruled that 42 U.S.C. § 300gg-13(a)(1) violates the Appointments Clause. *See* Sept. 7, 2022 Mem Op. & Order at 41. Second, the Court ruled that the PrEP coverage requirement, pursuant to the same statute, “violates Braidwood’s rights under RFRA.” *Id.* at 42.

Arthrex mandates that the appropriate response to the former violation is to “give full effect to the Constitution and to whatever portions of the statute are not repugnant to the Constitution, effectively severing the unconstitutional portion of the statute.” 141 S. Ct. at 1986. Thus, the Court should first issue an order declaring that the statutory provision that the Court determined renders subsection (a)(1) of the Preventive Services Provision unconstitutional must be disregarded. 42 U.S.C. § 299b-4(a)(6), the provision that prevents the Secretary from “direct[ing] PSTF to give a specific preventive service an ‘A’ or ‘B’ rating, such that it would be covered pursuant to 42 U.S.C. § 300gg-13(a)(1),” would accordingly no longer preclude the Secretary’s review of the PSTF’s recommendations for purposes of the Preventive Services Provision’s coverage requirements. Sept. 7, 2022 Mem. Op. & Order at 18 (quotation marks and citation omitted); *see* 42 U.S.C. § 299b-4(a)(6) (“All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.”). Once the Court orders Section 299b-4(a)(6) ineffective for purposes of the Preventive Services Provision, the Secretary will have the authority to direct specific coverage in the future and to ratify any past coverage requirements. This Secretarial oversight would cure any harm caused by the Appointments Clause violation the Court found, namely that coverage requirements are imposed by an officer who was not constitutionally appointed.

Second, having issued the order disregarding Section 299b-4(a)(6), the Court should, as a remedy for Braidwood's Appointments Clause claim, issue a declaration and injunction preventing Defendants from enforcing against Braidwood any coverage requirement imposed by subsection (a)(1) of the Preventive Services Provision pursuant to an "A" or "B" recommendation of the PSTF issued on or after March 23, 2010, unless and until any past recommendations are ratified by the Secretary or any future recommendations are issued under the Secretary's direction and supervision.⁷

Third, with respect to Braidwood's RFRA claim, the Court should issue a declaration and injunction preventing Defendants from enforcing the PrEP coverage requirement against Braidwood.

CONCLUSION

For the reasons set forth above, the Court should enter judgment for Defendants against all Plaintiffs except Braidwood because they lack standing. With respect to Braidwood, the Court should:

- First, order that 42 U.S.C. § 299b-4(a)(6) must be disregarded with respect to the Preventive Services Provision to the extent it precludes the Secretary's review and approval of the PSTF's recommendations for purposes of the Preventive Services Provision's coverage requirements, effectively severing it to restore the constitutionality of 42 U.S.C. § 300gg-13(a)(1), allowing the Secretary to direct and supervise recommendations of the PSTF in the future;
- Second, as a remedy for the portion of Braidwood's Appointments Clause claim on which it prevailed, issue
 - (a) a declaration that Braidwood need not comply with the coverage requirements imposed by 42 U.S.C. § 300gg-13(a)(1) resulting from any "A" or "B"

⁷ Defendants agree with Plaintiffs that 42 U.S.C. § 300gg-13(a)(1) does not violate the Appointments Clause insofar as it imposes coverage requirements of "A" or "B" recommendations of the PSTF issued prior to March 23, 2010 and that such requirements maintain their full force and effect.

- recommendation of the PSTF issued on or after March 23, 2010, unless and until any past recommendations are ratified by the Secretary or any future recommendations are issued under the Secretary's direction and supervision and
- (b) an injunction preventing Defendants from enforcing the same coverage requirements against Braidwood unless and until any past PSTF recommendations are ratified by the Secretary or any future recommendations are issued under the Secretary's direction and supervision; and
 - Third, with respect to Braidwood's RFRA claim, issue
 - (a) a declaration that Braidwood need not comply with the PrEP coverage requirement and
 - (b) an injunction preventing Defendants from enforcing the PreP coverage requirement against Braidwood.

Respectfully submitted,

CHAD E. MEACHAM
United States Attorney

/s/ Brian W. Stoltz
Brian W. Stoltz
Assistant United States Attorney
Texas Bar No. 24060668
1100 Commerce Street, Third Floor
Dallas, Texas 75242-1699
Telephone: 214-659-8626
Facsimile: 214-659-8807
brian.stoltz@usdoj.gov

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Christopher M. Lynch
CHRISTOPHER M. LYNCH
(D.C. Bar # 1049152)
Trial Attorney
U.S. Department of Justice
Civil Division
1100 L Street, NW
Washington, D.C. 20005
Telephone: (202) 353-4537
Fax: (202) 616-8470
Email: Christopher.M.Lynch@usdoj.gov

Attorneys for Defendants Xavier Becerra,
Janet L. Yellen, Martin J. Walsh, and the United States

Certificate of Service

On November 23, 2022, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties who have appeared in the case electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Christopher M. Lynch
Christopher M. Lynch